

AMENDMENTS TO THE SPECIFICATION

Please replace paragraph 0065 of the specification with the following paragraph. No new matter is being submitted with this amendment. Support may be found in originally filed paragraphs 0017, 0088, and 0089 and originally filed Figure 25.

[0065] Referring now to FIG. 3, the disc 10 comprises a first or upper endplate 20, a second or lower endplate 30, and a visco-elastic cushion 40 interposed between and adhered to the two endplates. The visco-elastic cushion 40 may comprise any of a variety of materials, such as, for example, a polymeric material. The upper and lower plates 20, 30 are substantially symmetrical about an anterior-posterior horizontally extending plane (a transverse plane shown in FIG. 2), as well as about a sagittal plane (FIG. 2). The terms “upper” and “lower” are used herein only for illustration purposes with reference to the orientation of the disc 10 when it is implanted in the human body between two adjacent vertebrae V1 and V2 (defined as the cephalad-caudal direction in FIG. 2). Indeed, the upper plate is more generally described as a first plate and the lower plate is more generally described as a second plate.

Please replace paragraph 0087 of the specification with the following paragraph. No new matter is being submitted with this amendment. Support may be found in originally filed Figure 25 and originally filed claims 20, 40, 62, 90, and 103.

[0087] The preferred disc 10 has certain load versus deflection characteristics that are similar to those found in the natural human disc. As was stated above, it is useful, once implanted, that the surgeon and patient can know the state of load experienced by the device. In this regard, referring to Figure 25, embodiments of the disc have, integral to its construction, strain gauges 38 or other means of force or pressure transduction. For illustration purposes only, not to be construed as limiting the invention thereto, the discussion will be directed to the use of strain gauges 38. An electronics package 380 having a ~~[[A]]~~transducer can be connected to signal conditioning and amplification circuitry on a micro scale in order to fit within the constraints of space available in the upper or lower endplate 20, 30. In this embodiment, the center stop is integral to the lower endplate 30 and consists of a hollow raised cylindrical platform 381. The space inside this ~~cylinder~~ raised platform 381 can house, for example, a 3 x 3 x 3 mm electronics package 380. The package can be wired to strain gauges 38 on the inside of the raised cylinder and in peripheral locations around the bottom endplate 30. Alternatively, the transduction means can be connected to electronics 380 such as piezoelectronics that eliminate the need for signal conditioning and amplification.

Referring now to Figure 25, there is shown an endplate having an internal region defined on one side by part of the endplate 30 and on an opposite side by a layer 383 that may connect with a compression stop. There may be a force transducer 38, such as a strain gauge, in the interior region directly adjacent to where the polymer (elastomer) 40

adjoins the endplate 30. There may be a force transducer 38, such as a strain gauge,
inside the compression stop. Inside the compression stop there may also be other
electronics 380 such as a microelectromechanical system, signal conditioning, telemetry,
or a coil. The layer 383 together with the rest of the endplate 30 may form a hermetic
seal enclosing electronics 380 within the internal region. The layer 383 may be laser-
welded to the rest of the endplate 30. Other types of force transducers 38 include
piezoelectric sensors.

*Please replace paragraph 0088 of the specification with the following paragraph.
No new matter is being submitted with this amendment.*

[0088] Since the center stop cylinder is not in contact with the polymer, the strain gauge 38 placed there will only measure contacts between the upper endplate and the center stop on the lower endplate. This data is useful in itself as an indicator of when loads are sufficiently high to engage the stop mechanism. However, in addition, more continuous data is available from peripherally placed strain gauges 38 that will measure stress in the endplate caused by compression, bending, torsion, and shear loads in all directions. This information can give a precise measure of the magnitude and direction of loads on the disc. FIGS. 22 and 25 depict how one embodiment of an artificial disc 10 uses strain gauges 38 to measure the load experienced by the prosthesis and relay that data on demand.

Please replace paragraph 0089 of the specification with the following paragraph. No new matter is being submitted with this amendment. Support may be found in original claims 105 and 106.

[0089] Placing the transducers within the polymer is not preferred since fatigue of wires or the introduction of stress risers within the polymer can lead to fatigue failure initiation sites. For these reasons, placing the signal conditioning microelectronics 380 within the center compression stop is advantageous. Once conditioned, the signal is telemeterized on demand through excitation of an internal coil from an inductively coupled external coil (not shown). This couple energizes the electronics 380 and transmits the data upon request. This mode of interrogating the device for its load condition can be done real time. In addition, the electronics package 380 may be provided with a data storage element capable of storing load history according to a preset sampling routine. Thus in interrogating the device, data may be[[or]] fed back from memory storage according to a preset sampling routine. It is also possible to sample the device remotely and wirelessly via the internet.

Please replace paragraph 0090 of the specification with the following paragraph. No new matter is being submitted with this amendment. Support may be found in original claims 42, 90, 108, and 109.

[0090] The data can indicate changes in the device since its implantation. It can also store load history to indicate if the patient is following doctor's orders for allowed activities. The power source for the memory-based data storage element is optionally a micro battery or a capacitor charged from the external inductive couple. The micro battery or capacitor may be part of the electronics package and may optionally be stored in the raised platform 381. The use of piezos is also possible. In one embodiment, a mylar flex circuit is pre-made and placed on the second endplate. Transducers or load or pressure sensors 38 may be ~~are~~ embedded on the mylar flex circuit and connected to the signal conditioning and amplifying electronics.

*Please replace paragraph 0092 of the specification with the following paragraph.
No new matter is being submitted with this amendment.*

[0092] Many possibilities exist for the manufacturing and the materials involved in an artificial intervertebral disc prosthesis according to the present invention. The endplates 20, 30 and/or endplate subplates 200, 300 may be of the materials described above. Further, they may have thicknesses in the range of approximately 1 mm to approximately 3 mm. Their surfaces may be surface-treated or machined for texture and bonding improvement. Examples of such treatments include but are not limited to ion etching, simple grit blasting, plasma spraying, or CNC machined geometry. Preferably the endplates 20, 30 (and/or 200, 300) are a CCM which is good in wear. The upper surfaces 21, 210 of the upper endplate 20 and upper subplate 200, and the lower surfaces 31, 310 of the lower endplate 30 and lower subplate 300, as well as the surfaces that interact with the visco-elastic cushion, may be coated with Titanium 6Al4V to improve bone interface and bonding. The second projection 370 can, as stated above, take many forms, including by way of mere examples, a cylinder, a post, a platform, and so forth. The preferred cylindrical member 381 is a solid projection from the lower endplate 20 or lower subplate 200. However, the cylindrical member 381 could be hollow so as to accommodate integral microelectronics diagnostics 380, as was discussed above.